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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA and NEW YORK STATE *ex rel.* FRANK BRANDT and CHRISTOPHER NORIA, Plaintiffs/Relators, - against - EAST COAST ORTHOTIC AND PROSTHETIC CORPORATION, VINCENT A. BENENATI, NYU LANGONE HEALTH, AND MAIMONIDES MEDICAL CENTER, Defendants.	**SECOND AMENDED COMPLAINT** CV 18-2600 (NG)

Plaintiffs the United States of America and the State of New York *ex rel.* Frank Brandt and Christopher Noria ("Relators"), by and through Relators' attorneys, Robert W. Sadowski PLLC, allege for their complaint as follows:

PRELIMINARY STATEMENT AND NATURE OF THE ACTION

1. This is a civil action brought by Relators on their own behalf and on behalf of the United States of America ("United States") and the State of New York against East Coast Orthotic and Prosthetic Corporation ("East Coast"), Vincent A. Benenati ("Benenati,"), NYU Langone Health ("NYU") and Maimonides Medical Center ("MMC") and (collectively, East Coast, Benenati, NYU, and MMC are referred to herein as "Defendants") under the False

Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "False Claims Act"), the New York False Claims Act, New York State Finance Law §§ 187 *et seq.*, (the "New York False Claims Act"), and section 6002 of the Affordable Care Act (the "ACA") and New York State Education Law: Professional Misconduct N.Y. C.L.S. Educ. § 6509-a, to recover damages sustained by, and penalties owed to, the United States and the State of New York as the result of Defendants having knowingly presented or caused to be presented to the United States and the State of New York false claims for the payment of funds disbursed under the Medicare Program, 42 U.S.C. §§ 1395c-1395i-4, and Medicaid Program, 42 U.S.C. §§ 1396 *et seq.*, and other state and federally funded health care programs, in excess of the amounts to which Defendants were lawfully entitled, from on or about 2009 through the present, as more specifically detailed *infra*.

2. These claims are based on Defendants' submission of false and fraudulent patient claims to the United States and the State of New York in order to obtain millions of dollars in payments for various healthcare services from 2009 through the present.

3. East Coast participated in an illegal kickback scheme and financial arrangements with Defendant medical providers to obtain lucrative Medicare and Medicaid referrals. East Coast, in accord with established company practice, engaged in such financial relationships with physicians, practice groups, hospitals and others in return for patient referrals in violation of the Stark Statute, 42 U.S.C. § 1395nn, its implementing regulations, 42 C.F.R. § 411.350 *et seq.* (collectively, the "Stark Laws") and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), Section 6002 of the Affordable Care Act (ACA) and then submitted or caused to be submitted false and fraudulent claims and statements to the United States and the State of New York, and received payments for services rendered to patients referred by those physicians, practice groups, hospitals and other health care providers.

4. East Coast offered remuneration to referring physicians by entering into illegal exclusive contractual joint venture services agreements, whereby it induced physicians, practice groups to refer to it numerous Medicare and Medicaid patients. Physicians, practice groups, and East Coast in turn, billed Medicare, Medicaid, and other government healthcare programs for those services. Pursuant to the illegal joint venture, East Coast provided physicians and practice groups, with orthotists, prosthetists, inventory, and inventory management directly on site in the physician's offices, at no cost to the physicians. The physicians could then bill Medicare and Medicaid for these products and services, dramatically increasing physician profit. In some instances, East Coast billed Medicare and Medicaid directly and then would pay the referring physician a percentage of the total billed amount East Coast received from Medicare and Medicaid. Payments made to physicians, directly or indirectly, by a medical product manufacturer must be reported to the Centers for Medicare and Medicaid Services ("CMS") Open Payments Portal, as is required under Section 6002 of the ACA, also known as the Physician Payments Sunshine Act ("PPSA"). East Coast has made such payments to physicians but has failed to disclose any of these payments to CMS since the PPSA's inception in 2013.

5. Defendants directly and indirectly caused physicians and practice groups to submit false claims to and obtained millions of dollars in payments from the United States and the State of New York, which were each tainted by the violation of the Anti-Kickback Statute and the Stark Laws, and therefore each violated the False Claims Act.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the claims brought under the False Claims Act and the New York False Claims Act pursuant to 31 U.S.C. § 3730(b)(1), 28 U.S.C. §§ 1331, 1345, and 1367.

7. Venue lies in this District pursuant to 31 U.S.C. §§ 3732(a) and (b), and 28 U.S.C. §§ 1391(b) and 1391(c), because Defendants are headquartered and located in this District, do business in this District, and because many of the acts complained of herein took place in this District.

PARTIES

8. Plaintiffs are the United States of America on behalf of its agency the United States Department of Health and Human Services ("HHS") and the State of New York on behalf of its agency the Department of Health ("DOH").

9. Relators reside in New York State. Each Relator has personal knowledge of the facts and is an original source of inside information, which they have voluntarily provided to the Government.

10. East Coast is a corporation organized under the laws of New York, with its principal office at 75 Burt Drive, Deer Park, New York 11729, that provides orthotics, prosthetics, and orthotic-related services.

11. Vincent A. Benenati is the Chief Executive officer of East Coast.

12. NYU and MMC are health care providers that entered into illegal exclusive contracts with East Coast to provide orthotics and orthotics-related services.

THE LAW

A. The Medicare Program

13. The United States, through HHS, administers the Medicare Program for the aged and disabled and was established by Title XVIII of the Social Security Act. 42 U.S.C. §§ 1395 *et seq.* Part A of the Medicare Program provides federal payment for patient institutional care, including hospitals, skilled nursing facility, and home healthcare. 42 U.S.C. §§ 1395c-1395i-4. Part B of the Medicare Program provides supplemental insurance coverage for medical and other services that are not covered by Part A. 42 U.S.C. §§ 1395j-1395w-4.

14. The Centers for Medicare and Medicaid Services ("CMS") is the governmental body responsible for the administration of the Medicare Program.

15. Under the Medicare Program, CMS makes payments to medical providers, such as physicians and orthotic and prosthetic providers, for inpatient and outpatient services after the services are rendered. For all practitioners and suppliers eligible to receive payments under Part B of Medicare can choose to enter into a participation agreement with Medicare. The Medicare Program participation agreements with hospitals, physicians, and other medical providers govern their participation in the program and the assignments of Medicare Part B payment for services. All Durable Medical Equipment, Prosthetics Orthotics and Suppliers ("DMEPOS") and Durable Medical Equipment ("DME") suppliers must submit the CMS 855S form to the National Supplier Clearinghouse ("NSC") to process for Medicare enrollment. Under Medicare, reimbursement is prohibited if the item or service is not "reasonable and necessary for the diagnosis and treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1)(A).

16. Outpatient services, such as outpatient medical equipment like orthotic and prosthetics and related services, are paid based on a fee schedule in accordance with Section

1833(h) of the Social Security Act. Part B "Participating Providers" are paid at 100 percent of the physician fee schedule.

17. In order to be reimbursed by Medicare, a provider must enroll in the Medicare program and submit an enrollment application to CMS. Every such enrollment application contains a "Certification Statement" that must be signed by an appointed official of the provider, such as its chief executive officer. The appointed official is required to certify, in pertinent part, that:

> "I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 1B of this application. The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Stature, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the Social security Act) and the Physician Self-Referral Law (Stark Law), 42 U.S.C. section 1395nn (section 1877 of the Social Security Act))."

CMS Form 855S.

18. Upon information and belief, at all times relevant hereto, Defendants were required to and did submit a Medicare enrollment application to CMS as they are a documented Medicare-approved supplier listed on the Medicare Approved Supplier list. [1]

19. Upon information and belief, at all times relevant hereto, appointed officials of NYU and MMC signed the Certification Statement contained in such enrollment applications.

B. The Medicaid Program

20. The Medicaid program was created under Title XIX of the Social Security Act to provide healthcare benefits for poor and disabled individuals. 42 U.S.C. §§ 1396-1396v. The Medicaid program is funded by both state and federal funds, with the federal contribution

[1] https://www.medicare.gov/medical-equipment-suppliers/detail?ptan=1174920001&location=11729&radius=10&cba=undefined

computed separately for each state. 42 U.S.C. §§ 1396b, 1396d(b). Medicaid is administered at the federal level by CMS. Federal involvement in Medicaid is largely limited to providing matching funds and ensuring that the states comply with minimum standards in the administration of the program.

21. The federal Medicaid statute sets forth the minimum requirements for state Medicaid Programs to qualify for federal funding, which is called federal financial participation ("FFP"). 42 U.S.C. §§ 1396 *et seq.*

22. Upon information and belief, defendants sought reimbursement from the Medicaid Program for the time period pertinent to this Complaint.

C. Physician Payment Sunshine Act (PPSA)

23. In February 2013, the U.S. Centers for Medicare & Medicaid Services (CMS) released regulations to implement the Physician Payments Sunshine Act ("PPSA") also known as section 6002 of the Affordable Care Act and is often referred to as Open Payments. This Act requires that all applicable medical product manufacturers who obtain reimbursement for their products through Medicare to report to CMS any payments made to physicians or teaching hospitals.[2]

24. Pursuant to 42 U.S.C. § 1320a-7h(a)(1)(A),

> "On March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary, in such

[2] "The term "applicable manufacturer" means a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States." 42 U.S.C. § 1320a-7h(e)(2).

> electronic form as the Secretary shall require, the following information with respect to the preceding calendar year: (i) The name of the covered recipient.[3]
> (iii) The amount of the payment or other transfer of value.
> (iv) The dates on which the payment or other transfer of value was provided to the covered recipient.
> (v) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as-
> (I) cash or a cash equivalent;
> (II) in-kind items or services;
> (III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or
> (IV) any other form of payment or transfer of value (as defined by the Secretary).
> (vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as- (I) consulting fees; (II) compensation for services other than consulting; […] (XV) any other nature of the payment or transfer of value (as defined by the Secretary).
> (vii) If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply."

42 U.S.C. § 1320a-7h(a)(1)(A).

> "(B) Special rule for certain payments or other transfers of value. In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient."

42 U.S.C. § 1320a-7h(a)(1)(B).

25. As a manufacturer of medical devices and a contracted supplier for which payment is available under Medicare, East Coast is required to disclose to CMS certain payments or other transfers of value to physicians, pursuant to the PPSA and PPSA regulations. The Plaintiff has a reverse-false claim under the PPSA, 42 U.S.C. § 1320a-7h, and associated regulations, 42 C.F.R. § 403.900-.9142 ("PPSA Regulations"), against East Coast arising from the following conduct from August 1, 2013 (when the PPSA was implemented) to today,

[3] Under the Open Payments Program ("OPP"), "the term "covered recipient" means the following: (i) A physician. (ii) A teaching hospital. (iii) A physician assistant, nurse practitioner, or clinical nurse specialist." 42 U.S.C. § 1320a-7h(e)(6).

whereby East Coast failed to report to CMS the value of East Coast's payments or transfers of value to or at the direction of covered recipients (Physicians with whom they have a Service Agreement). As relevant here, East Coast is required to disclose both indirect and direct payments they make to physicians, pursuant to their compensation arrangement set forth under the Services Agreement (Ex. 1). This compensation arrangement is explained above in detail. Each time ECOP bills Medicare for DME that they provide to a patient, East Coast renumerates ~45% of the DME fee-schedule amount for that device to the referring physician. Likewise, each time a physician bills Medicare for a DME device supplied to a patient by East Coast, the physician renumerates ~45% of the DME fee-schedule amount for that device back to East Coast (Ex. 1). *Each* of these payments, made by East Coast (an applicable manufacturer) to physicians with whom they have a Service Agreement with (covered recipients), have to be reported to CMS's open payments portal, however, there is no record of East Coast Prosthetic and Orthotics on this site.[4] From 2013 through the present, East Coast has failed to report to CMS the payments they have made to their contracted physicians. As a result of the Defendants' failure to comply with the Open Payments Program, they are liable for civil monetary penalties up to $8,000,000. 42 U.S.C. § 1320a-7h(b)(2).

26. Penalties under the PPSA:

> "**(b) Penalties for Noncompliance**
> (1) (A) any applicable manufacturer or applicable group purchasing organization that fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the

[4] The CMS Portal ECOP should be submitting data to https://openpaymentsdata.cms.gov/search/all-entities?name=East%20Coast%20Orthotic%20%26%20Prosthetic%20Corp

same manner as civil money penalties under subsection (a) of section 1320a–7a of this title are imposed and collected under that section.
(B) Limitation
The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $150,000.

(2) Knowing Failure to Report
(A) Subject to subparagraph (B), any applicable manufacturer or applicable group purchasing organization that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1320a–7a of this title are imposed and collected under that section.
(B) Limitation
The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $1,000,000.
42 U.S.C. § 1320a-7h(b).”

27. **“(b)DEFINITIONS.—**For purposes of this section—

(1)the terms “knowing” and “knowingly”—
(A)mean that a person, with respect to information—
(i) has actual knowledge of the information;
(ii) acts in deliberate ignorance of the truth or falsity of the information; or
(iii) acts in reckless disregard of the truth or falsity of the information; and
(B) require no proof of specific intent to defraud.”

31 U.S.C. § 3729.

28. East Coast hired a Compliance & Quality Assurance Officer in 2009, Mary Louise Lea, R.D., whose job is to make sure the company’s practices are in compliance with state and federal laws. (Ex. 2). Upon information and belief, East Coast’s compliance officer should be aware that the company, as an “applicable manufacturer” of DME, is required to disclose the payments they make to physicians, as set forth under the Physician Payment Sunshine Act (“PPSA”). Since East Coast should be aware of the federal requirement to report

such payments but has still failed to disclose these payments to CMS Open Payments since its inception in 2013, East Coast is liable for civil penalties up to $8,000,000 for knowingly failing to disclose such payments to CMS. 42 U.S.C. § 1320a-7h(b).

D. The Federal False Claims Act

29. The False Claims Act provides, in pertinent part, that:

> any person who –
> (A) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
> * * *
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,500 and not more than $11,000… plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729; 64 Fed. Reg. 47,099 (1999).

30. False certifications constitute false claims under the False Claims Act.

E. The New York False Claims Act

31. The New York False Claims Act provides in pertinent part that:

> "any person who:
> (a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> (c) conspires to commit a violation of paragraph (a), (b), (d), (e), (f) or (g) of this subdivision;
> * * *
> (g) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a local government;

> (h) . . . shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person."

New York State Finance Law §§ 189 (1)(a), (b), (c), (g), (h).

F. The Stark Laws

32. Enacted as amendments to the Social Security Act, 42 U.S.C. § 1395nn (commonly known as the "Stark Statute"), the Stark Statute prohibits a health care provider, such as an orthotic supplier, from submitting Medicare and Medicaid claims for payment based on patient referrals from physicians having a "financial relationship" (as defined in the statute) with the health care provider. The regulations implementing 42 U.S.C. § 1395nn expressly require that any provider collecting payment for a healthcare service "performed under a prohibited referral must refund all collected amounts on a timely basis." 42 C.F.R. § 411.353.

33. The Stark Laws (defined below) established the clear rule that the government will not pay for items or services prescribed by physicians who have improper financial relationships with other providers. In enacting the statute, Congress found that financial relationships between physicians and entities to whom they refer patients can compromise physicians' professional judgment as to whether an item or service is medically necessary, safe, effective, and of good quality. Congress relied upon various academic studies consistently showing that physicians who had financial relationships health care providers ordered more of those providers' services than physicians without those financial relationships. The Stark Laws (defined below) were designed specifically to reduce the loss suffered by the Medicare and Medicaid programs due to such questionable overutilization of services.

34. In 1993, Congress extended the Stark Statute ("Stark II" or "Stark Laws") to referrals for ten additional designated health services ("DHS"). Stark II also extended aspects of

the Medicare prohibition on physician referrals to Medicaid. *See* Omnibus Reconciliation Act of 1993, P.L. 103-66, §§ 13562, 13624; Social Security Act Amendments of 1994, P.L. 103-432, § 152. Section 13624 of the Omnibus Budget Reconciliation Act of 1993 extended aspects of the Medicare prohibition on physician referrals to Medicaid.

35. In pertinent part, the Stark Statute provides:

> (a) Prohibition of certain referrals
>
> (1) "In general
>
> Except as provided in subsection (b) of this section, if a physician (or immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2) then—
>
> (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter,
>
> (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third-party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A)."
>
> 42 U.S.C. § 1395nn (emphasis added).

36. The Stark Laws broadly define prohibited financial relationships to include any compensation paid directly or indirectly to a referring physician, subject to certain exceptions not applicable in this case. 42 C.F.R. § 411.354. The financial relationships that trigger the prohibition on referrals include any ownership or investment interest in the entity as well as any compensation arrangement with the entity, unless an exception applies. *Id.* Indirect financial arrangements in which the relationship is formed through an intervening third party are also included. *Id.* at 411.354(a)(2)(ii).

37. A *direct* financial relationship exists if remuneration passes between the referring physician and the entity furnishing DHS. *Id.* at 411.354(a)(2)(i). Remuneration means any payment or other benefits made directly or indirectly, overtly or covertly, in cash or in kind. 42

C.F.R. § 351. Remuneration includes the leasing of equipment and the provision of services and benefits.

38. A "referral" means a request by a physician for an item or service for which a payment may be made under Medicare, including a request for a consultation (including any tests or procedures ordered or performed by the consulting physician or under the supervision of the consulting physician), and the request or establishment of a plan of care by a physician that includes the furnishing of DHS (with certain exceptions for consultations by pathologists, diagnostic radiologists, and radiation oncologists). 42 U.S.C. § 1395nn(h)(5).

39. The Stark Laws prohibit the billing of DHS provided as a result of a prohibited referral. 42 C.F.R. § 411.353(b). An entity that receives a prohibited referral may not present a claim or cause the presentation of such claim to Medicare or Medicaid or other third-party payer for reimbursement of the services. *Id.*

40. An entity that collects payment for DHS that was performed under a prohibited referral **must refund all collected amounts on a timely basis.** *Id.* at 411.353(d).

41. 42 C.F.R. § 411.357(d) lays out the Personal Service Arrangement exception to the referral prohibition related to compensation arrangements. The law lays out eight conditions that must all be met for an agreement to qualify under this exception. The fifth condition, 411.375 (d)(1)(v) requires that,

> "The compensation to be paid over the term of each arrangement is **set in advance**, **does not exceed fair market value**, and, except in the case of a physician incentive plan (as defined at § 411.351), is **not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties."**
>
> 42 C.F.R. § 411.357(d)(1)(v) (Emphasis added).

42. Under 42 C.F.R. § 411.354(d)(1)(i),

> "Compensation is deemed to be "set in advance" if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items, services, office space, or equipment for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified."
>
> 42 C.F.R. § 411.354(d)(1)(i).

43. Under this act Fair Market Value is defined in 42 C.F.R. § 411.351 as,

> "The value in an arm's-length transaction, consistent with the general market value of the subject transaction." [General Market value is defined as] "With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other."
>
> 42 C.F.R. § 411.351.

44. As a result of the financial relationship between East Coast and practicing physicians, and that those physicians have made referrals to East Coast and East Coast and those physicians have submitted claims pursuant to such referrals, Defendants have violated the Stark Act. 42 U.S.C. § 1395nn(a)(1). "Both the Stark Act and the Anti-Kickback Act prohibit a health care entity from submitting claims to Medicare based on referrals from physicians who have a "financial relationship" with the entity, unless a statutory or regulatory exception (or "safe harbor") applies. 42 U.S.C. §§ 1395nn(a)(1); 1320a-7b(b)." (*United States ex rel. Singh v. Bradford Regional Med. Ctr.*, 752 F. Supp. 2d 602, 615 (W.D. Pa. 2010)). As discussed below, the East Coast Service Agreement does not meet the requirements for an exception to the referral prohibition related to compensation arrangements set forth under Stark. 42 C.F.R. § 411.357(d).

45. <u>The compensation is not "Set in Advance."</u> Stark requires that, "The compensation to be paid over the term of each arrangement is set in advance." 42 C.F.R. § 411.357(d)(1)(v). Stark defines "set in advance" and requires that "the formula for determining

the compensation must be set forth in sufficient detail so that it can be objectively verified." 42 C.F.R. § 411.354(d)(1)(i). On page three of the East Coast Service Agreement, the contract says that "(a) Provider agrees to pay contractor a fee for the Products and Services hereunder according to the Price List attached hereto as Exhibit "A"." (Ex. 1). Outside of the attached Price List, there is no written formula provided for determining compensation. However, the fees listed are not random. They are determined on a percentage of the product's fee schedule amount, for each DME device provided to the physician's patient, East Coast receives ~45% of the fee-scheduled amount listed and the doctor keeps the remaining ~55% of the product's fee. This compensation formula, however, is not written explicitly anywhere in the agreement, it can only be discovered if one was to examine the attached Price List and divide East Coast's fee by the fee-schedule amount listed next to each DME product. (Ex. 1). It is only then, that one could determine that the fees paid to East Coast/the physicians are a set percentage of the DME fee-schedule amounts. Since the compensation formula within the East Coast service agreement is not set forth in written detail, it cannot be considered "Set in Advance,", and as it fails to meet this requirement of 42 C.F.R. § 411.357(d)(1)(v), East Coast is prohibited from qualifying for an exception under this Act.

46. The Compensation exceeds Fair Market Value: Under 42 C.F.R. § 411.351 of the Act, fair market value must be consistent with general market value of the subject transaction and general market value requires that compensation for services must be between two parties who are "not otherwise in a position to generate business for each other." 42 C.F.R. § 411.351.[5]

[5] "[A]s a legal matter, a negotiated agreement between interested parties does not 'by definition' reflect fair market value. To the contrary, the Stark Act is predicated on the recognition that, where one party is in a position to generate business for the other, negotiated agreements

The East Coast Service Agreement lays out a business agreement in which the physicians who sign are anticipated/expected to generate business for East Coast by referring their patients to use East Coast's devices. (Ex. 3). The compensation arrangement within this agreement has the effect of inducing physicians to use East Coast devices.[6] This type of physician compensation arrangement clearly directs the participating physician to generate business for East Coast which is a violation of the fair market value provision of this Act.

47. The compensation is determined in a manner that takes into account the volume and value of anticipated referrals: In 2001, DHS and the Health Care Financing Administration (HCFA) issued a federal regulation in which CMS stated their interpretation of the "volume or value standard." They determined that,

> "A compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the arrangement in any manner that takes into account referrals or other business generated." (66 Fed. Reg. 856 at 877-878).

The business agreement between East Coast and the physicians with whom East Coast have a service agreement contains a compensation arrangement which is not reflective of Fair Market Value, as defined above. East Coast's compensation formula is directly dependent on the existence of referrals. East Coast is paid 45% of the fee-schedule amount of each medical device a physician refers a patient to use, if written mathematically, it would be: Physician

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between such parties are often designed to disguise the payment of non-fair-market-value compensation."
United States ex rel. Singh v. Bradford Regional Med. Ctr., 752 F. Supp. 2d 602, 624 (W.D. Pa. 2010).

[6] "If the payments **were intended to induce the physician to use Cardio-Med's services, the [Stark] statute was violated, even if the payments were also intended to compensate for professional services."** *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) (emphasis added). *See also United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989).

Compensation= .55(fee of device) or, East Coast Compensation= .45 (fee of device). Given this formula, if no patient is referred to East Coast for a medical device, then neither the physician nor East Coast would profit. Accordingly, this compensation model is *dependent* upon anticipated referrals. [7] According to CMS,

> "[W]e have determined that we will not consider the volume or value standard implicated by otherwise acceptable compensation arrangements for physician services solely because the arrangement requires the physician to refer to a particular provider as a condition of payment. So long as the payment is fixed in advance for the term of the agreement, is consistent with fair market value for the services performed *(that is, the payment does not take into account the volume or value of the anticipated* or required referrals), and otherwise complies with the requirements of the applicable exception, the fact that an employer or a managed care contract requires referrals to certain providers will not vitiate the exception."

66 Fed. Reg. 856 at 877 (emphasis added).

48. Additionally, the compensation a physician receives who signs East Coast's Services Agreement, varies upon the value and volume of referrals. Since the compensation model is based on a percentage of the DME fee schedule, the amount of compensation will naturally vary given the price (value) of the device, and the number (volume) of patients referred to East Coast for a device. Here, the compensation arrangement between the parties is greater than what would be paid in the absence of physicians' ability to provide referrals for East Coast. For example, if a Physician refers one patient to East Coast for a "Lumbar Sling" the fee schedule amount is $88.70, and the fee paid to East Coast is $39.92 (45% of $88.70) and the

[7] "Similarly, the regulation that addresses the physician's compensation exception states that the compensation may be conditioned on the physician's referrals so long as it meets all of the enumerated conditions, including that the compensation arrangement is "consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of *anticipated* or required referrals)." 42 C.F.R. § 411.354(d)(4)(ii) (emphasis added). Thus, we conclude that "anticipated referrals" are a proper consideration under the Stark Act." *United States ex rel. Singh v Bradford Regional Med. Ctr.*, 752 F. Supp. 2d 602, 624 (W.D. Pa. 2010).

doctor keeps $48.79 (55% of $88.70). (Ex. 1). The higher the fee scheduled amount for a single DME, the more each party is compensated. Similarly, the more patients are referred, the more money each party makes, as they each receive a percentage of the billed amount for every medical device, the more East Coast devices a physician refers to their patients, the greater the payout. In an email sent by Benenati, East Coast's CEO, to Dr. Henry Tischler, Benenati says, "How Profitable is it for a physician? On average, a single physician can see monthly profits of $10,000 after expenses. Of course, this is based on how busy and what their insurance mix is." (Ex. 3). In this email, East Coast's CEO explicitly says that the compensation paid to physicians is based on volume of patients and the value of their insurance mix. This compensation formula is in direct violation of Stark Exception for Personal Service Arrangements and Fair Market Value Compensation because it takes into account the volume and value of referrals made from a physician to East Coast.

> "The OIG has found that **compensation arrangements based on a percentage of sales "appear to be associated with an increased potential for program abuse."** OIG Advisory Opinion No. 99-3, 1999 HHS OIG Adv. Op. LEXIS 37, 1999 WL 34984727, at *6 (Mar. 23, 1999). These types of arrangements are subject to greater scrutiny, because their inclusion suggests that the parties' actions under the Agreement could be motivated by their desire and ability to increase sales of . . . products that might be paid for by federal or state health care programs. Regardless of which party was to be responsible for the marketing of the Zimmer products, the end result would be the same: the more products sold, the more money the parties would make. *Zimmer, Inc. v. Nu Tech Med., Inc.*, 54 F. Supp. 2d 850, 862-63 (N.D. Ind. 1999**). Courts have held that percentage-based compensation arrangements violate the AKS**. *See Zimmer*, 54 F. Supp. 2d at 862-63; *Nursing Home Consultants, Inc. v. Quantum Health Servs., Inc.*, 926 F. Supp. 835, 844 (E.D. Ark. 1996), *aff'd*, 112 F.3d 513 (8th Cir. 1997)."

MedPricer.com, Inc. v. Becton, Dickinson & Co., 240 F. Supp. 3d 263, 270-271 (D. Conn. 2017). (emphasis added).

49. East Coast's compensation arrangement with physicians is not reflective of fair market value and the compensation formula takes into account the volume and value of referrals. Accordingly, the East Coast Services Agreement is in violation of 42 U.S.C. § 1395nn and does not meet the requirements for an exception under Stark nor the AKS safe harbors because,

> "[A]ll of the exceptions and safe harbors listed above require that compensation under the arrangement be fair market value and not determined in a manner that takes into account the volume or value of referrals. (*Indirect Compensation Arrangement*, 42 C.F.R. § 411.357(p)(1); *Equipment Rental*, 42 U.S.C. § 1395nn(e)(1)(B)(iv), 42 C.F.R. § 411.357(b)(4), 42 C.F.R. § 1001.952(c)(5); *Space Rental*, 42 U.S.C. § 1395nn(e)(1)(A)(iv) &(v), 42 C.F.R. § 411.357(a)(4) & (5), 42 C.F.R. § 1001.952(b)(5); *Personal Services Safe Harbor*, 42 C.F.R. § 1001.952(d)(5); and *Fair Market Value Exception*, 42 C.F.R. § 411.357(l)(3).)"

United States ex rel. Singh v. Bradford Regional Med. Ctr., 752 F. Supp. 2d 602, 624 (W.D. Pa. 2010).

50. The East Coast Services Agreement mirrors that of the one in *United States ex rel. Singh v. Bradford Regional Med. Ctr.*, 752 F. Supp. 2d 602 (W.D. Pa. 2010). In this case a regional medical center (BRMC) entered into equipment sublease compensation arrangements with physicians to refer their patients to BRMC's for diagnostic nuclear imaging. The Court found that this agreement was inflated to compensate for the doctor's ability to generate anticipated referral revenue that was not fair market value under the Stark Act and thus violated of the Act.[8] The compensation arrangement contained in the Equipment Sublease agreement provided that BRMC paid physicians a billing fee equal to 10% of all collections for tests performed with BRMC's camera. The court decided that,

[8] "We conclude that the compensation arrangement between BRMC and the doctors is inflated to compensate for the [doctors] ability to generate other revenues." 66 Fed. Reg at 877. Specifically, we find that the amount of the compensation arrangement was arrived at by taking into account the anticipated referrals from the doctors. We therefore conclude that the compensation arrangement between BRMC and the doctors is not "fair market value" under the Stark Act." *Id.* at 633.

> "payment based on a percentage of collections, as is the 10% billing fee, is not covered by the provisions of 42 C.F.R. § 411.354(d)(2). *See* 66 Fed. Reg. at 877-878. Accordingly, we find that the aggregate **compensation received by the doctors based on the 10% billing fee varies with the volume or value of referrals generated by the doctors for BRMC,** and BRMC was aware of the fact that the 10% fee it paid to the doctors varied with the amount of referrals. **42 C.F.R. § 411.354(c)(2)(ii) & (iii). Therefore, the 10% billing fee arrangement constitutes an indirect compensation arrangement between the parties for the period of time it was in existence.**" *Id.* at 634. (emphasis added).

Accordingly, in this case, any payment East Cost makes or receives that is a percentage of the fee-schedule billed amount for a DME product, they are in violation of Stark.

51. The aggregate services provided under the agreement exceed what is "reasonable and necessary": The Agreement furnishes participating Physicians with several services East Coast employees may render under the subcontract, even going so far as to acknowledge the types of additional services explicitly not provided because these services would give the appearance of inducement for the benefit of referrals. Given the provision of these additional services— services for which the physician would have to hire the employees which the Agreement explicitly precludes them from doing, point "14. Independent Contractor Status" reads, in pertinent part, that "No employee of Contractor will be deemed to be an employee or servant of Provider" (Ex.1). However, at point "6." in this agreement they state, "**Provider may contract separately and independently with the employees of Contractor** to provide **services that are not contemplated by this Agreement**. In the event that Provider so contracts with the employees of Contractor, Contractor shall not, under any circumstances, receive any compensation, consideration or other benefit." (Ex. 1) (Emphasis added). This conflicting provisions make clear that the aggregate services covered by the arrangement **do** exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s). This qualification for exclusion is therefore demonstrably left unsatisfied.

52. The arrangement is not commercially reasonable if no referrals were made between the parties: The East Coast Service Agreement is a business arrangement based on the sole expectation of the participating physician's ability to generate income for East Coast by referring their patients to use East Coast's prosthetic and orthotic devices. This arrangement would hardly be commercially reasonable (much less viable) if referrals were not made between the parties. The provision of free office space to East Coast employees would not be reasonable if the Physicians couldn't anticipate that such a provision would yield reimbursement in accordance with the percentage compensation for referrals made to East Coast. No physician would provide free office space to a DME supplier absent the belief that such an arrangement would have a net benefit on their overhead costs (including but not limited to those for administrative (including billing) services). Nor would the consignment arrangement of DME be commercially reasonable (much less viable) for East Coast unless they were assured that Physicians would consistently refer patients to them. Absent the assurance of anticipated referrals, this consignment agreement would be of no benefit to East Coast.

53. 42 C.F.R. § 411.357(d)(1)(vi) requires that "The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law." This provision suggests that the arrangement cannot be in violation of the anti-kickback statute in order to qualify for Stark's physician services compensation exception. 42 C.F.R. § 411.357(d)(1)(vi). Under Stark, "Does not violate the anti-kickback statute" means that the compensation arrangement "Meets a safe harbor under the anti-kickback statute, as set forth at § 1001.952 of this title, ''Exceptions.'" 42 C.F.R. § 411.351. East Coast's Service Agreement with physicians does not meet a safe harbor under the AKS and therefore, fails to meet yet another requirement for this Stark exception (infra).

G. The Anti-Kickback Statute

54. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these difficult to detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. First enacted in 1972, Congress strengthened the statute in 1977 and again in 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b; Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

55. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for federally funded medical services, including services provided under the Medicare, Medicaid, and TRICARE programs. 42 U.S.C. § 1320a-7b(b).

56. The Anti-Kickback Statute criminalizes such actions as:

> "(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> > (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both."

42 U.S.C. § 1320a-7b(b)(2)(A)-(B).

57. The term "any remuneration" encompasses any kickback, bribe, or rebate, direct or indirect, overt or covert, in cash or in kind. 42 U.S.C. § 1320a-7b(b)(1).

58. The AKS provides a safe harbor for Personal services and management contracts. 42 C.F.R. § 1001.952(d). This safe harbor applies only if all of the standards under this exception are met.

> **"d)** Personal services and management contracts. As used in section 1128B of the Act, "remuneration" does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as **all** of the following seven standards are met (emphasis added) --
> **(i)** The agency agreement is set out in writing and signed by the parties.
> **(ii)** *The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.*
> **(iii)** If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
> **(iv)** The term of the agreement is for not less than one year.
> **(v)** *The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.*
> ***(vi)*** *The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.*
> **(vii)** *The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.*"

42 C.F.R. § 1001.952(d) (emphasis added).

59. East Coast's service agreement with participating physicians does not satisfy all conditions necessary to qualify for safe harbor under 42 C.F.R. § 1001.952(d). Specifically, this agreement fails to satisfy conditions (ii), (v), (vi) and (vii). (Ex. 1).

60. East Coast's Agreement fails to satisfy the second condition for safe harbor under AKS in that the agreement fails to cover all the services to be provided by the agent to the principal. Under Section 6 (Provision of Facilities) of the Agreement, Contractors emphasize that "Contractor's personnel who utilize the Facilities shall only perform functions contemplated under this Agreement, and will not provide any other services to Provider (*i.e.*, cast tech responsibilities, medical assistance, secretarial, administrative or otherwise) which could be perceived as a benefit to Provider to induce the referral of business by Provider to Contractor." (Ex. 1) (Emphasis added). However, immediately thereafter, this provision of the Agreement provides a work-around, whereby "**Provider may contract separately and independently with the employees of Contractor** to provide **services that are not contemplated by this Agreement**. In the event that Provider so contracts with the employees of Contractor, Contractor shall not, under any circumstances, receive any compensation, consideration or other benefit." (Ex. 1) (Emphasis added).

61. While East Coast acknowledges and proports to ensure against the furnishing of services that would give the appearance of a benefit for the purpose of inducement, they also immediately thereafter furnish the parties with an avenue through which they may provide these additional services. As was previously elaborated upon in our discussion of the Stark safe harbors, even granting that Physicians may contract separately for services not stipulated under an agreement, the safeguard makes clear that such contracts would require that separately contracted East Coast employees must be deemed employees of the Physician to qualify, which East Coast's agreement explicitly precludes Providers from doing. (Ex. 1) Thus, whichever way East Coast slices it, their agreement fails to specify all services to be rendered, and reference to the latter half of their provision of facilities section is unavailing.

62. The elements of the fifth condition of the AKS safe harbor closely coincide with those presented under the fifth safe harbor requirement set under Stark (42 C.F.R. § 411.357(d)(1)(v)) in that both require that compensation be set in advance, be consistent with fair market value, and not take into account volume or value of referrals or other business generated. As demonstrated in the Stark safe harbor analysis above, East Coast's Agreement does not satisfy the conditions necessary to qualify for safe harbor under Stark, and for this reason similarly does not qualify for safe harbor under the AKS.

63. East Coast's Agreement fails to satisfy the conditions necessary to qualify for the sixth safe harbor exception under AKS because the arrangement involves the "counselling or promotion of a business arrangement," evidenced by various email correspondences between East Coast personnel. (Ex. 4, 5, 6, 7, & 9).

64. In an April 7th, 2017, email titled "Quarterly Review/Incentive", East Coast employee Mark Rodman poses the following questions to fellow East Coast personnel: "How many of you speak to your doctors daily and truly try to get an understanding of what their patient's needs are? When given the opportunity to suggest items to the doctors do you? Do we try to **promote certain products over others?**" He then goes on emphasize that, "[w]e need to ramp up our sales and continue to push every day to **get that one more item**. We can do that by **making suggestions to the doctors and communicating with them daily**." (Ex. 4) (emphasis added). Rodman closes the email by emphasizing "[the] great potential to get an item prescribed if you happen to be in the doctor's sight." (Ex. 4). The dynamic illustrated by this email is one in which Contractors participate in active marketing and direct contact with physicians and patients, presenting a significant risk of undue influence in the referral of patients to East Coast,

particularly in the referral of "certain products over others" like custom DME that fetches higher returns for physician and contractor alike. (Ex. 4).

65. In a September 30th, 2017, email titled "[SBUH] MUST READ: TLSO and Miami J's", John Benenati informs East Coast personnel that "…Dr. Morelli stated he **only wants custom TLSO** for he never wants LSO! Whenever ortho residents call please make sure we let the residents [k]now this. IF they ask for a prefab TLSO let them know that **Dr. Morelli told us he only wants custom TLSOs.**" (Ex. 5) (emphasis added). Absent case-by-case evaluations it would hardly seem reasonable for a physician to insist on custom DME for all their patients, which certainly begs the question of whether such "customs" are medically necessary. Considering his demonstrable financial incentive to refer patients for custom DME as per the percent-based compensation arrangement reflected in the Price List (Ex. 1), his insistence that all patients receive customs is highly suspect, and this communication with East Coast personnel certainly appears to promote the business relationship he has with East Coast.

66. In a May 21, 2015 email from East Coast employee, John Feliciano, to East Cost personnel, he set out a protocol for employees to follow and ends with, "IF ANY DOCTORS HAVE A PROBLEM WITH THIS… THEY CAN COME TALK TO ME." (Ex. 9). This language suggests that East Coast has a curious and perhaps, unethical relationship with the doctors they work with as this employee clearly feels he is in a position to give doctors orders when it is for the benefit of East Coast business.

67. These email correspondences lay bare a dynamic in which East Coast personnel actively promote their business arrangement with Providers, demonstrably failing to satisfy this condition necessary to qualify for safe harbor under AKS.

68. The elements of the seventh condition of the AKS safe harbor echo those set under the third condition of the Stark Law safe harbor (42 C.F.R. § 411.357(d)(1)(iii)) in that both require that aggregate services covered by the arrangement must be "reasonable and necessary" for the legitimate business purposes of the arrangement (referred to under the AKS safe harbor condition as being "necessary to accomplish the commercially reasonable business purpose of the services"). As was demonstrated in the previous section regarding Stark safe harbors, East Coast's Agreement similarly does not meet the conditions necessary to qualify for safe harbor under this condition of the AKS safe harbor.

69. In sum, both AKS and Stark prohibit health care providers from billing Medicare for certain designated services referred by a physician with whom the provider has a financial relationship of any type not falling within specific statutory exceptions. 42 U.S.C. § 1395nn.

H. New York Codes, Rules, and Regulations (NYCRR)

70. 18 NYCRR § 515.2: Unacceptable practices under the medical assistance program:

> "(b)**(5)** Bribes and kickbacks. Unless the discount or reduction in price is disclosed to the client and the department and reflected in a claim, or a payment is made pursuant to a valid employer-employee relationship, the following activities are unacceptable practices:
> **(i)** soliciting or receiving either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for referring a client to a person for any medical care, services or supplies for which payment is claimed under the program;
> **(ii)** soliciting or receiving either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program;
> **(iii)** offering or paying either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for referring a client to a person for any medical care, services or supplies for which payment is claimed under the program; or
> **(iv)** offering or paying either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care,

services or supplies for which payment is claimed under the program." 18 N.Y.C.R.R. § 515.2(b)(5).

71. 18 N.Y.C.R.R. § 515.3: Authority to Sanction:

> **"(a)** Upon a determination that a person has engaged in an unacceptable practice, the department may impose one or more of the following sanctions:
> **(1)** exclusion from the program for a reasonable time;
> **(2)** censure; or
> **(3)** conditional or limited participation, such as requiring preaudit or prior authorization of claims for all medical care, services or supplies, prior authorization of specific medical care, services or supplies, or other similar conditions or limitations.
> **(b)** The department may also require the repayment of overpayments determined to have been made as a result of an unacceptable practice.
> **(c)** Whenever the department sanctions a person, it may also sanction any affiliate of that person; provided, however, that in imposing a sanction upon an affiliate, the determination must be made on a case-by-case basis giving due regard to all the relevant facts and circumstances leading to the original sanction.
> **(d)** In determining whether or not to sanction a person, the department may hold that person responsible for the conduct of another person. However, conduct may only be imputed to another when the persons are affiliates of each other, and the conduct was accomplished within the course of the duties of the person to be sanctioned and the other person knew or should have known of the conduct, or the conduct was effected with the knowledge and consent of the other."

18 N.Y.C.R.R. § 515.3.

72. East Coast's compensation arrangement with physicians, in which they share a set percentage of the billing for each referral that physician supplies East Coast, is in direct violation of 18 N.Y.C.R.R. § 515.2(b)(5)(ii) and 18 N.Y.C.R.R. § 515.2(b)(5)(iii). As a result of this unacceptable practice, East Coast should be sanctioned under 18 N.Y.C.R.R. § 515.3.

I. New York State Education Law: Professional Misconduct

73. N.Y. C.L.S. Educ. § 6509-a.

> "That any person subject to the above enumerated articles, has directly or indirectly requested, received or participated in the division, transference, assignment, rebate, splitting or refunding of a fee for, or has directly requested, received or profited by means of a credit or other valuable consideration as a commission, discount or gratuity in connection with the furnishing of professional care, or service, including […] hospital or medical supplies, physiotherapy or other therapeutic service or equipment, artificial

> limbs, teeth or eyes, orthopedic or surgical appliances or supplies, optical appliances, supplies or equipment, devices for aid of hearing, drugs, medication or medical supplies or any other goods, services or supplies prescribed for medical diagnosis, care or treatment under this chapter[…]". N.Y. C.L.S. Educ. § 6509-a.

74. N.Y. C.L.S. Educ. § 6511

> "The penalties which may be imposed by the board of regents on a present or former licensee found guilty of professional misconduct (under the definitions and proceedings prescribed in sections sixty-five hundred nine and sixty-five hundred ten of this article) are: (1) censure and reprimand, (2) suspension of license, (a) wholly, for a fixed period of time; (b) partially, until the licensee successfully completes a course of retraining in the area to which the suspension applies; (c) wholly, until the licensee successfully completes a course of therapy or treatment prescribed by the regents; (3) revocation of license, (4) annulment of license or registration, (5) limitation on registration or issuance of any further license, (6) a fine not to exceed ten thousand dollars, upon each specification of charges of which the respondent is determined to be guilty[…]." N.Y. C.L.S. Educ. § 6511.

75. East Coast's Service Agreement provides for compensation to be renumerated to physicians based on a percentage of the billing fee for each DME product that the physician refers to a patient. (Ex. 1). This type of compensation arrangement is classified as fee-splitting and constitutes as professional misconduct, as set forth under N.Y. C.L.S. Educ. § 6509-a. Accordingly, East Coast is liable for penalties related to professional misconduct, as set forth under N.Y. C.L.S. Educ. § 6511. The defendants' fee-splitting arrangement is very similar to an arrangement found in in the case of *Hartman v. Bell*. In that case, "The contract […] provided for the plaintiff to receive 20% of the gross receipts from the defendants' practice of industrial medicine […]." *Hartman v. Bell*, 137 A.D.2d 585, 585-586 (2d Dep't 1988). The court determined that, "the agreement in question constituted a voluntary prospective arrangement for the splitting of fees in contravention of Education Law § 6509-a and State public policy *(see, Psychoanalytic Center v. Burns*, 46 N.Y.2d 1002, *rearg. denied*, 47 N.Y.2d

951; *United Calendar Mfg. Corp. v. Huang*, 94 A.D.2d 176) […]." ***Hartman v. Bell***, 137 A.D.2d 585, 585-586 (2d Dep't 1988).

76. 18 N.Y.C.R.R. § 360-7.5(c)

> **"**A provider of medical care, services, or supplies may employ a business agent, such as a billing service or an accounting firm. Such agent may prepare and send bills and receive MA payments in the name of the provider only if the compensation paid to the agent is:
> **(1)** reasonably related to the cost of the services;
> **(2)** unrelated, directly or indirectly, to the dollar amounts billed and collected; and
> **(3)** not dependent on actual collection of payments."

77. 18 N.Y.C.R.R. § 504.9(a)(1)

> "[…] payment may be made only to the provider of the medical care, services or supplies; […] or if the practitioner has a contract under which the facility or organization submits the claims; or to a business agent, including a service bureau, billing service, or accounting firm, if the payment is made in the name of the provider and *the agent's compensation* for the services is related to the cost of processing the claim, *is not related on a percentage or other basis to the amount billed or collected, and is not dependent upon collection of the payment.*"

18 N.Y.C.R.R. § 504.9(a)(1) (emphasis added).

78. As per East Coast's Services Agreement, they state that the contractor (under the Contractor Services (a)) will "(iii) fax or hand-deliver charge sheets to Provider's biller; (iv) Obtain authorization from patients' insurance carriers for prescribed products." (Ex. 1). Additionally, under "Provider Responsibilities" the contract stipulates that "Provider will be responsible for all management and administrative services in connection with the provision of the Products and Services to Provider's patients as contemplated under this Agreement, including billing […]." (Ex. 1). Under "Billing; Compliance with Billing Rules & Regulations" the agreement states that, "(a)Provider shall be entitled to bill patients and their insurance carriers […] and collect fees for all Services and all Products provided to its patients as set forth under this agreement. Contractor shall not be entitled to bill or collect any such fees. (b)

Contractor may assist Provider in establishing billing process […].” (Ex. 1). While this agreement makes clear that the Contractor (East Coast) shall not bill for products and services, East Coast does in fact bill for orders. On an East Coast advertisement to doctors, they specifically say, “East Coast Bills your practice.” (Ex. 7). Under East Coast’s Site-Specific Information, each practice East Coast operates out of is listed along with the doctors and practice specifics- including how each practice bills. Out of the practices listed, East Coast does all the ordering and billing for approximately 50% of the practices, and for approximately 50% of the other practices, “ECOP still processes orders for carriers the MD cannot bill.” (Ex. 8). This billing system not only violates the term of the Services Agreement East Coast has with these physician practices, but it also is in violation of 18 N.Y.C.R.R. § 360-7.5(c)(2) and 18 N.Y.C.R.R. § 504.9(a)(1). Under this law, persons submitting claims on behalf of a provider of medical care are acting as that provider’s business agent and cannot be compensated “on a percentage or other basis to the amount billed or collected, and is not dependent upon collection of the payment.” 18 N.Y.C.R.R. § 504.9(a)(1). East Coast is in violation of this statute because for each claim they submit on behalf of a provider, they receive ~45% of the billed amount for the product and renumerate ~55% back to the provider.[9] As a provider’s business/billing agent, East Coast cannot be paid a percentage of the amount billed for any product or service, but as per

[9] “These regulations contain clear prohibitions against the type of payment arrangement contained in the CSC-NYC contract.” *See* 18 N.Y.C.R.R. § 360-7.5(c)(“[A business] agent may prepare and send bills and receive MA payments . . . only if the compensation paid to the agent is . . . unrelated, directly or indirectly, to the dollar amounts billed and collected.”); 18 N.Y.C.R.R. § 504.9(a)(1) (“[P]ayment may be made only to . . . a business agent . . . [if] the agent’s compensation for the services is related to the cost of processing the claim, is not related on a percentage or other basis to the amount billed or collected, and is not dependent upon collection of the payment.”).
(*United States ex rel. Forcier v. Computer Sciences Corp.*, 2017 U.S. Dist. LEXIS 128140, at *21-22 (S.D.N.Y. 2017)

their Services Agreement with providers, this is exactly how East Coast is compensated (Ex. 1).[10]

J. Contractual Joint Ventures

79. Contractual joint ventures between physician referrers of business and providers such as those providing durable medical equipment are inherently suspect as violations of the Anti-Kickback Statute and the Stark Laws.

80. In 2003, and again in 2006, the Office of the Inspector General issued bulletins and advisory opinions that list the characteristic of prohibited arrangements. Special Advisory Bulletin, Contractual Joint Ventures, Department of Health and Human Services, Office of Inspector General, April 2003, at http://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf ("2003 Bulletin"); OIG Advisory Opinion No. 06-02, Department of Health and Human Services, Office of Inspector General, March 21, 2006, at https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/ao0602.pdf ("2006 Advisory Opinion").

81. The first characteristic of a prohibited "joint venture" is when the provider seeks to expand into a line of ancillary services that can be provided to the provider's existing patients. *See* 2003 Bulletin.

82. The second characteristic of a prohibited "joint venture" is when the new line of business predominantly or exclusively services the owner's existing patient base, and the provider does not intend to expand the provider's business to service other patients. *Id.*

[10] "A DOH guidance document issued in 2001 reiterates that billing agents "charging Medicaid providers a percentage of the amount claimed or collected" could lead to the State seeking refunds of payments made to such agents." *Id.* at *9.

83. The third characteristic of this prohibited venture is the limited business risk for the provider. The provider's primary, perhaps sole, contribution to the new business is referrals. There is no *bona fide* business risk to the provider. *Id.*

84. The fourth characteristic of this prohibited venture is that the supplier is a potential competitor. *Id.*

85. The fifth characteristic of this prohibited venture is the broad scope of the services provided to the referring physician, with the physician's major contribution being referrals. *Id.*

86. The sixth characteristic of this prohibited venture is where remuneration is tied to volume and value. *Id.*

87. Finally, the seventh characteristic of this prohibited venture is its exclusivity. *Id.*

THE FACTS

THE IMPROPER FINANCIAL RELATIONSHIP AND KICKBACK SCHEME

88. During the relevant time period, East Coast was aware of the prohibitions and restrictions on its financial relationships with referring physicians. This information was known to the East Coast's officers, including, but not limited to its Chief Executive Officer, Vincent A. Benenati. Despite this knowledge, East Coast initiated a plan to target certain physicians and physician practice groups and enter into unlawful financial relationships to induce physicians to make patient referrals to East Coast, including referrals of Medicare and Medicaid patients. East Coast either itself or knowingly caused those physicians to bill for and collect millions of dollars in reimbursement from the United States and New York State based on the services East Coast provided for those referred patients.

89. As described by Benenati himself in a solicitation to the Brooklyn Spine and Arthritis Center:

> "About five years ago [2009], we started working with practices with an optional business model where we provide the same services to the practice but the practice (physician) bills for the services and we are a subcontractor. Most insurance carriers reimburse physicians more than we as a company get reimbursed, so this has become a win-win situation for both parties involved.
>
> How profitable is it for a physician? On average, a single physician can see monthly profits of $10,000 after expenses. Of course, this is based on how busy and what their insurance mix is. We provide a multitude of services in this model; we provide the inventory (at no cost to the practice), the Orthotist or Orthotic Fitter (who would work in your practice full time, once again, at no charge to the facility) and we would handle all the authorizations for the products that we provide at your location. We have an implementation team that will work with your billing department and monthly go over denials and any billing issues or concerns. On patients that your practice can not [sic] bill, East Coast Orthotic & Prosthetic Corp. will bill those carriers directly." (Ex. 3).

90. In Benenati's January 21, 2014 solicitation, he touted: "Some notable practices that have successful implemented with [sic] this model include SUNY Buffalo, Columbia Orthopedics, practices at NYU, Hospital for Special Surgery and Westchester Medical Center. We have over 150 orthopedic surgeons involved, with new practices joining us monthly." (Ex. 3).

91. Benenati claimed that East Coast "has been on-site at SUNY Downstate for the last 14 years and we also used to come [to] . . . Methodist [Hospital in Brooklyn], working with Dr. Michael Vitale a number of years ago." (Ex. 3).

92. East Coast's arrangement was memorialized in an "Orthotic and Prosthetic Services Agreement" (the "Agreement"). Under the Agreement, East Coast was the "Contractor" and the physician or practice was denoted as the "Provider."

93. Under the Agreement, the Contractor agreed to perform the following services for the Provider:

- Supply services and orthotic and prosthetic devices ("Product") in accordance with a Price List attached to the Agreement;

- Order, fit and finish custom Products in accordance with the Price List;
- Deliver charge sheets to Provider's biller;
- Obtain authorization from patient's insurance carriers for prescribed Product; and
- Provide orthotists, orthotic fitters, and/or prosthetists to apply braces and prosthetics, perform casting/measuring for custom devices, train patients on Product usage; and supply patients with wear and care information. (Ex. 1).

94. The prices reflected in the Price List "are all-inclusive prices and incorporate charges for all of the Services" supplied by the Contractor. *Id.*

95. The Agreement provides that the orthotists, orthotic fitters, and prosthetists will be available at **all** of the Provider's locations during normal business hours, and on call outside of normal business hours, including weekends. *Id.*

96. The Agreement provides that the Contractor "shall be the exclusive contractor providing Services in **all** of Provider's locations." *Id.*

97. According to the Agreement, the Provider is responsible for "all management and administrative services in connection with the provision of the Products and Services to . . . patients . . . including billing, secretarial, and scheduling." *Id.*

98. Under the Agreement, the "Contractor will maintain in the supply room or locker in the premises of the Provider premises . . . an inventory of Products . . . for the use by Provider." *Id.*

99. The Agreement states that "Provider shall be entitled to bill patients and their insurance carriers (and other third-party payors) and collect fees for all Services and all Products provided to its patients . . ." *Id.*

100. The Price List attached to the Agreement lists the Products by HCPS code, description, Medicare allowable reimbursement and the charge East Coast bills the Provider for each Product. According to the Price List, East Coast charges the contracting Provider 45% of the Medicare allowable reimbursement on each Product East Coast provides. *Id.*

101. Under the Agreement, East Coast provides incredible value to Providers on site at the physician's own office: (1) Personal services to order, fit, cast, take measurements, to obtain prior authorizations, to train patients, to supply wear and care information, and to assist the physician in billing and collections ("Services"); and (2) Product. *Id.*

102. Moreover, for each Product provided to the Provider, Contractor bills the Provider 45% of the Medicare allowable reimbursement for that Product. This set percentage does not take into account any of the Services provided to or by the Provider *(i.e.*, fitting the orthotics, assisting in billing and collections) or the fair market value of the specific product.

103. The Agreement states that the "Contractor's fees for the Products and Services provided under this Agreement are the fair market value thereof, negotiated at arms-length, and are not inflated or reduced to take into account business generated between the parties." (Ex. 1). Given that the price charged to the physicians is always 45% of the Medicare Fee-Schedule amount for the Product, regardless of the amount of effort involved, the amount of Service provided, or the actual cost of the item, this statement is false.

104. Instead, each charge by East Coast to providers should be the combination of two components: (1) the Services provided to the physician's office and patient; and (2) the fair market value of each Product provided.

105. In actuality, East Coast charges the physician nothing for the Services component. Providing services free-of-charge in the physician's own office is an incentive to the physician to make referrals. (Ex.1).

106. The East Coast Agreement bears every characteristic of an illegal arrangement violating the Anti-Kickback Statute and the Stark Laws.

107. First, the second Whereas clause of the Agreement states "Provider wishes to establish a program to provide Products ancillary to Provider's orthopedic surgery practice and to be able to bill insurers and other payors for such Products . . . ." (Ex. 1). This demonstrates that the Provider seeks to expand into a line of ancillary services that can be provided to the Provider's existing patients.

108. Second, the intent of the Agreement is to capture another avenue of billing payors, without any expansion of the Provider's operation or patient base.

109. Third, in East Coast's Agreement, the Provider is not asked to take any financial risks. All of the Products needed to fit and treat the physician's patients are owned by East Coast. The business only exists by virtue of the referrals of patients by the physician to East Coast.

110. Fourth, absent the Agreement, East Coast would have had to compete for the referral of services. Indeed, the Providers could potentially provide the services themselves and compete with East Coast. However, given the exclusivity provision of the contract, in addition

to the East Coast practitioners actively stationed at the Provider's offices, and the free provision of Services, Providers are contractual incentivized to refer the business to East Coast.

111. Indeed, here, the relationship between defendants is so close that East Coast states in its letter of solicitation to the Brooklyn Spine and Arthritis Center that for patients for whom a physician practice cannot bill, East Coast will bill those patient's insurance carriers directly.

112. Fifth, the Agreement provides that East Coast will provide essentially all the services. East Coast offers what appears to be a "turnkey" operation, including day to day management, billing, equipment, personnel, supplies, and inventory. East Coast provides every essential component needed to operate a durable medical equipment company to the physician, including the inventory, prior authorizations, training of patients, casting and measuring, providing trained personnel to fit the patients, assistance with billing and collections, and East Coast will even assist the physician with government audits. All the physicians need to do is refer their patients.

113. Sixth, the practical effect of the Agreement is to provide the Providers with the ability to collect revenue for services provided by East Coast. The amount of the remuneration to the physician will vary with the value and volume of referrals generated for the venture by the physician. East Coast bills the physician on a case-by-case basis for the Products they provide to the physician's patients and so the amount East Coast bills the physician varies from month to month based on the number of referrals the physician gives to East Coast each month. (Ex. 3).

114. Finally, the Agreement provides that East Cost will be the exclusive Contractor in all of the physician's offices.

115. Specific Examples of Prohibited Practices:

116. On or about April 7, 2017, Mark Rodman, Regional Manager-Long Island, Queens, and Brooklyn, informed the staff of East Coast who worked in the field that each Staff member who fit certain devices would receive $25.00. The devices included in this incentive pay included: knee unloader, custom knee brace, LSO (631 or 637), or bone stimulator. These are all high reimbursement devices. (Ex. 4).

117. On or about April 7, 2017, Mark Rodman wrote to the technicians who work with physicians, the following: "When given the opportunity to suggest items to the doctor[,] do you? Do we try to promote certain products over others? I was at one site one day and the doctor wanted something more than a cock-up wrist splint but didn't want to put the patient in a cast[,] I suggested the EXOS, he loved it and uses them more now (they pay much hire (sic) too). Another location gives out wrap around knee braces like crazy. Perhaps those patients if they have OA [osteoarthritis] should be getting an unloader brace (another high price item)." (Ex. 4). The April 7 email also alerts the technicians of the $25.00 incentive payment for certain products.

118. East Coast has a contract with New York Methodist Hospital's RYC Orthopaedics where an East Coast employee works. On October 23, 2017, Medicare beneficiary RD was prescribed a Spanlink RAD shoulder system universal by doctor Craig Capeci. The East Coast employee assigned to New York Methodist filled out the Patient Product Agreement & Proof of Delivery and Documentation of Medical Necessity, which was then signed by Dr. Capeci. The East Coast employee performed all aspects of seeking any necessary approvals, filling out paperwork, including the prescription and fitting the equipment.

119. On October 2, 2017 Medicare beneficiary JW was prescribed a RED2XL Hinged Knee Brace with Spacer Fabric, 2XL by doctor Craig Capeci. The East Coast employee

assigned to New York Methodist filled out the Patient Product Agreement & Proof of Delivery and Documentation of Medical Necessity, which was then signed by Dr. Capeci. The East Coast employee performed all aspects of seeking and necessary approvals, filling out paperwork, including the prescription and fitting the equipment.

120. East Coast has a contract with Maimonides Medical Center. On April 10, 2015, Dr. John Munyak, with an office at 6010 Bay Parkway, 6th Floor, Brooklyn NY 11204, was delivered equipment from East Coast for three patients.

121. There are two types of prohibited arrangements that East Coast uses, in one arrangement a billing company affiliated with East Coast (known as ECOP) processes orders and performs billing for health care provides who do not have arrangements with carriers.

122. In the other arrangement known as "Wholesale," the health care provider bills the insurer, such as Medicare and Medicaid and pays East Coast 45% of the fee-scheduled price for the prosthetic. East Coast is pushing its contracted health care providers to the Wholesale method.

123. The health care providers who currently have contracts with East Coast include the following institutions and Orthopedists have prohibited contracts with East Coat: RYC Orthopedics at 1056 5th Avenue, New York, New York 10028; Maimonides Bone & Joint Center at 6010 Bay Parkway, Brooklyn, NY 11204; and all NYU facilities including NYU Langone Seaport Orthopedics at 233 Broadway, Suite 640, New York 10279; NYU Langone Ambulatory Care—Long Island at 1999 Marcus Avenue, Suite 306, Lake Success, NY 11042. (Ex. 8).

124. By entering into the Agreement with numerous providers, East Coast and the identified providers violated the Stark Laws and the Anti-Kickback Statute. Therefore, each time healthcare Providers or ECOP billed Medicare and Medicaid for orthotic service provided

for a patient referred to East Coast under the Agreement, defendants knowingly submitted a false claim to Medicare and Medicaid, which East Coast knowingly caused them to make.

SUMMARY AND CONCLUSION

125. East Coast and their contracted healthcare Providers have demonstrated their knowingly willful scheme to evade the requirements of the Stark Laws, the Anti-Kickback Statute, and other applicable rules and laws, to receive payments from Medicare, Medicaid and other federal healthcare programs that they are not entitled to, by their schemes and prohibited financial relationships with their referring physicians.

CLAIM ONE

Violations of the False Claims Act (31 U.S.C. § 3729 (a)(1)(A)) Presenting False Claims for Payment

126. Plaintiffs incorporate by reference paragraphs 1 through 125 above as if fully set forth herein.

127. The United States seeks relief against Defendants under Section 3729(a)(1)(A) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

128. As set forth above, Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. Defendants, knowingly or acting with deliberate ignorance or with reckless disregard for the truth, presented, or caused to be presented, to an officer, employee or agent of the United States, false and fraudulent claims for payment or approval in connection with the submission of its requests for reimbursement under the Medicare, Medicaid and other federal healthcare programs.

129. The United States paid Defendants under the Medicare, Medicaid and other federal healthcare programs because of Defendants' fraudulent conduct.

130. By reason of the Defendants' false claims, the United States has been damaged in a substantial amount to be determined at trial.

CLAIM TWO

Violations of the False Claims Act
(31 U.S.C. § 3729 (a)(1)(B))
Use of False Statements

131. Plaintiffs incorporate by reference paragraphs 1 through 125 above as if fully set forth herein.

132. The United States seeks relief against Defendants under Section § 3729(a)(1)(B) of the False Claims Act, 31 U.S.C. 3729(a)(1)(B).

133. As set forth above, Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. Defendants, knowingly or acting in deliberate ignorance or in reckless disregard for the truth, made, used, or caused to be made and used, false records and statements, in order to get false or fraudulent claims paid or approved by the United States in connection with the submission of its requests for reimbursement under the Medicare, Medicaid and other Federal healthcare programs.

134. The United States paid such false or fraudulent claims because of Defendants' acts and conduct.

135. By reason of Defendants' false claims, the United States has been damaged in a substantial amount to be determined at trial.

CLAIM THREE

Violations of the False Claims Act
(31 U.S.C. § 3729 (a)(1)(G))
Use of False Statements

136. Plaintiffs incorporate by reference paragraphs 1 through 125 above as if fully set forth herein.

137. The United States seeks relief against Defendants under Section § 3729(a)(1)(G) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

138. As set forth above, Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. In addition, As set forth above, East Coast knowingly failed to report any and all payments they made to physicians, to the CMS Open Payments Portal, since its inception in 2013.

139. By reason of the Defendants' failure to report, the federal government has been damaged and deprived of necessary information material to their administration of the ACA and East Coast is liable for civil penalties up to $8,000,000 for knowingly failing to disclose such information to the CMS Open Payments Portal. 42 U.S.C. § 1320a-7h(b).

140. However, Defendants have knowingly or acting in deliberate ignorance or in reckless disregard for the truth, made, used, and caused to be made and used, false records and statements, in order to conceal, avoid, or decrease the obligation to pay or transmit money or property to the United States in connection with the submission of its requests for reimbursement under the Medicare, Medicaid and other federal healthcare programs, in violation of AKS, Stark, ACA and the FCA.

141. Defendants failed to pay or transmit money due to the United States because Defendants' acts and conduct.

142. By reason of the Defendants' use of false statements, the United States has been damaged in a substantial amount to be determined at trial.

CLAIM FOUR

Violations of the False Claims Act
(31 U.S.C. § 3729(a)(1)(C))
Conspiracy to Commit Violations of the False Claims Act
(Against All Defendants)

143. Plaintiffs incorporate by reference paragraphs 1 through 125 above as if fully set forth herein.

144. The United States seeks relief against Defendants under Section 3729(a)(1)(C) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

145. As set forth above, Defendants conspired to commit a violation of subparagraph (A), (B), and (G) of the False Claims Act. Defendants have committed at least one overt act in furtherance of their conspiracy.

146. By reason of the Defendants' conspiracy, the United States has been damaged in a substantial amount to be determined at trial.

CLAIM FIVE

Violation of the New York False Claims Act
(NY State Finance Law § 189 (1)(a))
Presenting False Claims for Payment

147. Plaintiffs incorporate by reference paragraphs 1 through 125 above as if fully set forth herein.

148. The State of New York seeks relief against Defendants under Section 189 (1)(a) of the New York False Claims Act, NY State Finance Law § 189 (1)(a).

149. As set forth above, Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. However, Defendants, knowingly or acting with deliberate ignorance or with reckless disregard for the truth, presented, or caused to be presented, to an officer, employee or agent of the State of New York, false and fraudulent claims for payment or approval in connection with the submission of Defendants' requests for reimbursement under the

Medicaid and other New York state healthcare programs in violation of the Stark Laws and Anti-Kickback Statute.

Defendants engaged in illegal fee-splitting by paying their referring physicians a percentage of the billing fee for each DME product East Coast provides to physicians' patients, this practice is in violation of N.Y. C.L.S. Education Law § 6509-a and 18 N.Y.C.R.R. § 504.9(a)(1).

150. The State of New York paid Defendants under the Medicaid and other New York state healthcare programs because of Defendants' fraudulent conduct.

151. By reason of Defendants' conduct, the State of New York has been damaged in a substantial amount to be determined at trial.

CLAIM SIX

Violation of the New York False Claims Act
(NY State Finance Law § 189 (1)(b))
Use of False Statements

152. Plaintiffs incorporate by reference paragraphs 1 through 125 above as if fully set forth herein.

153. The State of New York seeks relief against Defendants under Section 189 (1)(b) of the New York False Claims Act, NY State Finance Law § 189 (1)(b).

154. As set forth above, the Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. Defendants, knowingly or acting in deliberate ignorance or in reckless disregard for the truth, made, used, or caused to be made and used, false records and statements, in order to get false or fraudulent claims paid or approved by the State of New York in connection with the submission of Defendants' requests for reimbursement under the

Medicaid and other New York state healthcare programs in violation of the Stark Laws, the Anti-Kickback Statute and 18 N.Y.C.R.R. § 515.2.

155. The State of New York paid Defendants under the Medicaid and other New York state healthcare programs because of Defendants' fraudulent conduct.

156. By reason of Defendants' conduct, the State of New York has been damaged in a substantial amount to be determined at trial.

CLAIM SEVEN

Violation of the New York False Claims Act
(NY State Finance Law § 189 (1)(g))
Use of False Statements

157. Plaintiffs incorporate by reference paragraphs 1 through 125 above as if fully set forth herein.

158. The State of New York seeks relief against Defendants under Section 189 (1)(g) of the New York False Claims Act, NY State Finance Law § 189 (1)(g).

159. As set forth above, the Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. Defendants, knowingly or acting in deliberate ignorance or in reckless disregard for the truth, made, used, and caused to be made and used, false records and statements, in order to conceal, avoid, or decrease the obligation to pay or transmit money or property to the State of New York in connection with the submission of Defendants' requests for reimbursement under the Medicaid and other New York state healthcare programs in violation of the Stark Laws and the Anti-Kickback Statute.

160. Defendants failed to pay or transmit money due to the State of New York because of Defendants' acts and conduct.

161. By reason of Defendants' acts and conduct, the State of New York has been damaged in a substantial amount to be determined at trial.

CLAIM EIGHT

Violation of the New York False Claims Act
(NY State Finance Law § 189 (1)(c))

162. Plaintiffs incorporate by reference paragraphs 1 through 117 above as if fully set forth herein.

163. The State of New York seeks relief against Defendants under Section 189 (1)(c) of the New York False Claims Act, NY State Finance Law § 189 (1)(c).

164. As set forth above, Defendants conspired to commit a violation of subparagraphs (1)(a)), (1)(b), and (1)(g) of the New York False Claims Act. Defendants have committed at least one overt act in furtherance of their conspiracy.

165. By reason of the Defendants' conspiracy, State of New York has been damaged in a substantial amount to be determined at trial.

WHEREFORE, plaintiffs the United States and the State of New York *ex rel.* Frank Brandt and Christopher Noria request that judgment be entered in their favor and against Defendants as follows:

(a) On the First, Second, Third, and Fourth Claims for relief (Violations of the False Claims Act, 31 U.S.C. § 3729(a) (1) (A), (B), (C) and (G), for treble the United States' damages, in an amount to be determined at trial, plus a monetary penalty for each false claim; and

(b) Awarding relators' share pursuant to 31 U.S.C. § 3730(d)(1) or (2); and

(c) On the First, Second, Third, and Fourth Claims for Relief, an award of costs and attorney's fees pursuant to 31 U.S.C. § 3730(d); and

(d) On the Fifth and Sixth, Seventh, and Eighth Claims for relief , Violations of the New York False Claims Act, NY State Finance Law § 189 (1) (a), (b), (c), and (g), for treble the State of New York's damages, in an amount to be determined at trial, plus a monetary penalty for each false claim; and

(e) Awarding relators' share pursuant to NY State Finance Law § 190(6); and

(f) On the Fifth, Sixth, Seventh, and Eighth Claims for Relief, an award of costs and attorney's fees pursuant to NY State Finance Law § 190(7); and

(g) Awarding such further relief as is proper.

JURY TRIAL IS DEMANDED

Dated: New York, New York
April 23, 2021

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